



VATAP SHORT REPORT:
Temporal Artery Thermometry
in the Post-operative Setting
DECEMBER 2006

Item	Yes	Partly	No
Preliminary			
1. Appropriate contact details for further information?	√		
2. Authors identified?	√		
3. Statement regarding conflict of interest?			√
4. Statement on whether report externally reviewed?	√		
5. Short summary in non-technical language?	√		
Why?			
6. Reference to the question that is addressed and context of the assessment?	√		
7. Scope of the assessment specified?	√		
8. Description of the health technology?	√		
How?			
9. Details on sources of information?	√		
10. Information on selection of material for assessment?	√		
11. Information on basis for interpretation of selected data?	√		
What?			
12. Results of assessment clearly presented?	√		
13. Interpretation of the assessment results included?	√		
What Then?			
14. Findings of the assessment discussed?	√		
15. Medico-legal implications considered?	√		
16. Conclusions from assessment clearly stated?	√		
17. Suggestions for further actions?	√		

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This summary form is intended as an aid for those who want to record the extent to which a HTA report meets the 17 questions presented in the checklist. It is NOT intended as a scorecard to rate the standard of HTA reports – reports may be valid and useful without meeting all of the criteria that have been listed.



VA Technology Assessment Program

SHORT REPORT

Temporal Artery Thermometry in the Post-operative Setting

Number 9

Rapidly produced brief assessments of health care technology

December, 2006

Executive Summary

The temporal artery thermometer (TAT) uses infrared technology to measure skin temperature over the forehead area, as a proxy for measuring core temperature. Recent marketing efforts have extolled the advantages of using TAT for noninvasive temperature measurement in a range of populations.

VA Technology Assessment Program was asked to evaluate the scientific evidence of the clinical utility of TAT in adult patients immediately following surgery. The information was required within a few days, necessitating a focused, rapid, qualitative systematic review of the best available evidence from the peer reviewed literature. The results would be used to inform the development of new quality measures in VA post-operative patient care.

The review found a lack of conclusive evidence supporting the clinical use of TAT as an instrument for measuring core temperature in adult inpatient populations. The best available evidence consists of two preliminary studies comparing the diagnostic accuracy of TAT to pulmonary artery catheter measurement in mixed adult inpatient populations with conflicting results.

Several investigators with institutional experience with newer thermometry devices like TAT have called for improved study quality and quality monitoring of new products in the appropriate clinical setting with a range of suitable patients to confirm their safe use and clinical value before adopting more widely. Given the state of the current evidence base, this would be a reasonable recommendation for VA to follow at this time.

Background

The VA National Director of Anesthesia asked the VA Technology Assessment Program (VATAP) to evaluate the scientific evidence on the clinical use of temporal artery thermometry in patients immediately following surgery. This information will be used to inform new quality measures in VA post-operative patient care.

The temporal artery is connected directly to the heart through the carotid artery and runs superficially at the lateral aspect of the forehead. Its properties and location make it readily accessible for temperature measurement and, theoretically, provide a reliable perfusion rate with which to approximate arterial temperature at the heart.

Developed originally by Exergen Corporation (Watertown, MA; www.exergen.com), the temporal artery thermometer (TAT) is a hand-held, battery operated device that uses infrared technology to measure skin temperature over the temporal artery. Their product became commercially available in 1999 as the TemporalScanner™ Temporal Artery Thermometer. The TemporalScanner™ and its competitors are marketed with FDA 510(k) pre-market approval in regulatory Class II (see Table 1) for the intermittent measurement of human body temperature of people of all ages (FDA 2001; FDA 2003; FDA 2005).

Table 1. FDA-approved temporal artery thermometers

Manufacturer	Device name
Exergen Corp. Watertown MA	TemporalScanner™ Thermometer, formerly known as SensorTouch
Hubdic Co. Limited Bonita Spring, FL	Digital Forehead Thermometer FS-100
AViTA Corp. Flagstaff, AZ	AviTA TS8/TS9 Series IR Ear/Forehead Thermometer

For TAT to be incorporated into routine clinical use, it must confer advantages over existing technology for temperature measurement, namely comparable or superior diagnostic accuracy and, to a lesser extent, consistency over expected temperature ranges. TAT is reported to be safe, fast, easy to use and well-tolerated by pediatric and adult patients.

Exergen Corp. bases their support for the clinical use of TAT in hospitalized adults on a non-peer reviewed meeting abstract describing 130 adult patients studied in a Coronary Care Unit and a Surgical Intensive Care Unit (Carroll 2003). This study concluded that temporal artery temperature was as accurate as core temperature measured by the gold standard pulmonary artery catheter; this same study also found no correlation between pulmonary artery temperature and oral temperature. However, such claims should be critiqued for study quality and the context in which different temperature measurement sites are to be measured, and also should be confirmed in rigorous peer reviewed literature before widespread clinical use.

Assessment Methods

Because the client required the information within a few days, VATAP undertook a rapid, qualitative systematic review that focused on the best available evidence from the peer reviewed literature of the clinical utility of TAT in adult subjects studied in the post-operative setting with emphasis on its diagnostic performance.

Search strategy

In April 2006, VATAP conducted comprehensive searches on MEDLINE, PUBMED, EMBASE®,

the Cochrane Library® and Current Contents® using descriptors for temporal artery thermometry, body temperature, arterial temperature, and infrared thermometry. The FDA Center for Devices and Radiological Health and manufacturer web pages were searched for information relating to regulation and clinical use of temporal artery thermometry.

VATAP queried its colleagues in the International Network of Agencies for Health Technology Assessment via its electronic listserv on April 26, 2006 for completed HTA reports or ongoing reviews on the subject.

Inclusion criteria

Studies were included in the review if they evaluated the diagnostic performance of TAT compared with core temperature using a gold standard in adult hospitalized subjects in the post-operative setting. Excluded from the review were studies published in languages other than English, studies of only pediatric patients, studies of devices not commercially available in the US, or abstracts without full text.

Quality appraisal

For a quality appraisal of included studies, VATAP applied elements of the Standards for Reporting of Diagnostic Accuracy framework (STARD 2001).

Results

The electronic searches identified 85 citations for this report. Review of titles and abstract information in the searches and in hand searches of reference lists of retrieved articles identified 11 studies comparing TAT to another thermometry device, of which:

- Five compared TAT to core temperature measured with PAC (4) or esophageal probe (1);
- Eight were in children;
- One was published in a language other than English.

Two studies met criteria for inclusion in the review (Myny 2005; Suleman 2002). No HTA reports or systematic reviews on this topic were identified from either the searches or direct contact with HTA colleagues.

The best available evidence of the diagnostic accuracy of TAT in adult subjects in the post-operative setting consists of two small studies of mixed inpatient populations, comprising medical and post-surgical patients in the intensive care setting in one study (Myny 2005) and adult and pediatric cardiac patients in the immediate post-operative period in the other (Suleman 2002). The results are abstracted and summarized in Table 2.

Suleman (2002) tested the precision and accuracy of TAT in 15 adults and 16 children who developed mild fever after cardiopulmonary bypass; in adults the core temperature range ranged from 35.4°C to 38.4°C over the study period. Temperature measurement was recorded at 15 minute intervals throughout recovery with TAT vs. pulmonary artery catheter (PAC) in adults or vs. bladder catheter in children. TAT correlated poorly with core temperature readings in adults, although somewhat better in children, and was insufficiently precise for routine clinical use in either population of patients recovering from cardiopulmonary bypass.

Myny and colleagues (2005) prospectively compared simultaneous TAT and axillary temperature (AT) readings to indwelling PAC readings in a mixed sample of 57 adult medical and post-surgical ICU patients with normothermia (range: 36.2°C to 38.0°C), some of whom received vasopressor therapy. Comparing AT and PAC readings, the investigators reported TAT had “relatively good reliability with an acceptable accuracy and variability in the normal temperature range”. However, the authors did not feel that the results of TAT conferred any substantial benefit over rectal, oral or bladder thermometry when they compared their findings to the findings in the general literature.

Summary and Discussion

The best evidence in the peer-reviewed published medical literature published in English of the clinical use of TAT used in adult patients is confined to two preliminary studies evaluating the diagnostic accuracy of TAT in a range of inpatients with normothermia (Myny 2005) and in post-operative cardiac patients who exhibited wider temperature variability (Suleman 2002).

Both studies compared TAT to pulmonary artery catheter measurement as the gold standard; the use of blinded readings was not reported. Conflict in the results from these two studies can be attributed primarily to different study populations and the range of core temperature represented. Although Myny (2005) found no differences in TAT measurements in patients with or without vasopressor therapy, this and forehead sweating should be documented as they may further confound results. Suleman (2002) noted that their results were restricted to a study population for whom better methods of temperature measurement are readily available, suggesting a need for a compelling reason to replace more optimal thermometric devices already in use.

A third study (Ostrowsky 2003), which did not meet criteria for inclusion in the review because no comparison to a gold standard was performed, illustrates the consequences of adopting technology too quickly based on the manufacturer's claims without conclusive scientific evidence to confirm their findings. In this serial survey of TAT readings, the clinical staff observed consistently low temperature readings with TAT despite clinical indications of fever among some of their patients, even after staff retraining and education. Temperature readings were confirmed with oral mercury thermometry in some patients, prompting a more comprehensive institutional review of performance data for quality monitoring.

Subsequent to the completion of the final draft of this report in April 2006, VATAP identified a newly published systematic review of the accuracy of noninvasive core temperature measurement in acutely ill, hospitalized adult patients (Hooper 2006). Hooper (2006) included studies of TAT published through March 2005, while VATAP reviewed evidence published through April 2006. Both reviews are consistent in their findings regarding the lack of conclusive evidence supporting the use of TAT as an accurate instrument for measuring core temperature in adults.

Implications for VHA

Based on the conflicting and preliminary nature of the evidence base, the routine use of TAT in adults in the post-operative setting cannot be recommended at this time in VHA.

Several authors with institutional experience with newer thermometry devices like TAT have called for improved study quality and quality monitoring of new products in the appropriate clinical setting with a range of suitable patients to confirm their safe use and clinical value before adopting more widely (Myny 2005; Ostrowsky 2003; Rupp 2003; Holtzclaw 1998).

Thermometry studies that measure body temperature during the immediate post-operative period need to account for: 1) a range of temperatures at either extreme that may occur in these populations; 2) the use of vasopressors; 3) the presence of atherosclerotic disease or; 4) other conditions unique to post-surgical patients, while comparing the device of interest to appropriate estimates of core blood temperature circulating to the brain.

Holtzclaw (1998) provides additional guidance on appropriate designs of thermometry studies for measuring instrument accuracy, reliability, linearity and precision that may assist in interpreting studies and conducting future research on diagnostic test performance. She further discusses identification of the optimal

site for measuring body temperature (and the optimal device with which to measure it) based on the purpose of the information, for example, to determine if body temperature is within the safe range for the brain and central nervous system or to determine changes in heat distribution.

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Table 2. Diagnostic accuracy studies of temporal artery thermometry in adult hospitalized patients

Study characteristics	Suleman (2002)	Myny (2005)
Objective	To evaluate precision and accuracy of TAT in adult and pediatric patients post cardiopulmonary bypass (CPB)	To evaluate the accuracy and variability of the TAT in adult ICU patients
Study population	N=30 adults, 26 children recovering from CPB surgery 15 adults and 10 children excluded due to no fever (12 adults, 9 children) or forehead sweating (3 adults, 1 child)	<ul style="list-style-type: none"> N = 57 adult orally intubated patients with indwelling PAC in a university teaching hospital from Nov 2001-March 2002: 32 admitted to MICU; 25 admitted to SICU 318 total measurements taken serially ≥ 4 hours apart: TAT, AT and PAC taken within 3 min of each other Use of vasopressors was recorded: n=33 with, n=24 without Device supplied by manufacturer for evaluation purposes
Study perspective	Prospective	Prospective
Reference standard	<ul style="list-style-type: none"> PAC (adults) Bladder catheter (children) 	PAC
Test methods	<ul style="list-style-type: none"> TAT Temps recorded at 15 min intervals for the first 3 hours of post op recovery or for a total of 3 hours if core temp increase was observed Measurements performed by a single investigator trained in the use of TAT Blinding of test measure to reference standard not reported 	<ul style="list-style-type: none"> TAT AT Simultaneous measures for all three devices take by 3 individuals within three minutes Time difference between measurements on patients with repeat measurements at least four hours Blinding of test measure to reference standard not reported
Device	SensorTouch™ by Philips, Inc. (patented by Exergen, Inc.)	Exergen TemporalScanner LXTA®
Statistical methods	Bland and Altman method for measuring agreement between two methods of clinical measurement	<ul style="list-style-type: none"> ANOVA, Tukey HSD test, student t-test P<0.05 = statistically significant
Outcome measure(s)	<ul style="list-style-type: none"> Correlation between devices, Clinically adequate differences between devices = $\pm 0.5^{\circ}\text{C}$ Se for detecting fever and Sp for detecting no fever 	Mean difference between device parings
Results	<p>Adults only reported (N=15)</p> <p>TAT (T_{st}) vs. PAC (T_{core}):</p> <ul style="list-style-type: none"> $T_{core} = 0.7T_{st} + 13$ $r^2 = 0.3$ (for 294 measurements) i.e. weak relationship between TAT and PAC Average temp difference between devices=$1.3 \pm 0.6^{\circ}\text{C}$; 89% of TAT differed from PAC by $> 0.5^{\circ}\text{C}$ TAT Se=0%, Sp=100% All TAT measures in adults $\leq 37.4^{\circ}\text{C}$, while 59% of PAC exceeded this value 	<ul style="list-style-type: none"> 318 measurements obtained: 29 patients assessed once, 15 patients twice, 13 patients ≥ 3 times. Mean temperature of all measurements was: PAC=37.1°C (SD± 0.87), TAT=37.0°C (SD± 0.68) and AT=36.6°C (SD± 0.94) TAT vs. PAC: mean difference=0.14°C; SD± 0.51; p= 0.33 PAC vs. AT: mean difference=0.46°C; SD± 0.39; p< 0.001 TAT vs. AT: mean difference=0.36°C; SD± 0.58; 95% CI: 0.25-0.48; p= 0.01 Agreement between PAC and TAT > agreement between PAC and AT, while variability was comparable. TAT in patients with vasopressor therapy (mean=0.12°C; SD± 0.55) vs. without vasopressor therapy (mean=0.19°C; SD± 0.48) (p= 0.47).
Conclusions/Comments	<ul style="list-style-type: none"> TAT is insufficient for clinical use in adult and pediatric post-operative cardiac patients To the extent that intense vasoconstriction or other factors unique to cardiac surgery contributed, performance may prove better in other patient populations Study limitation: results strictly apply to a special surgical population in whom PAC for core temperature measurement is already available Study limitation: regression analysis used dependent measures from the same patient, but design allowed for a clinically relevant temp range to be evaluated 	<ul style="list-style-type: none"> Relative to PAC, TAT has comparable accuracy and variability and relatively good reliability in patients with normothermia. The results are comparable to those of the AT, but they do not suggest any substantial benefit compared to rectal, oral or bladder thermometry reported in the literature. Study limitation: TAT use at temperatures not explored outside the normal range. Study limitation: only one or two measurements taken in 77% of the study population.
Abbreviations:	AT, axillary temperature ICU, intensive care unit PAC, pulmonary artery catheter Se, sensitivity	Sp, specificity TAT, temporal artery thermometry r^2 , coefficient of determination, measures the strength of the relationship between two sets of numbers

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